REMARKS

Claim 9 has been amended to clarify certain terms and to add steps, as suggested by the Examiner. Claim 9 has also been amended to clarify that the homozygous plant is a transgenic plant is homozygous for the gene encoding the compound. Claims 20 and 21 have been amended for consistency with the amendments to claim 9. New claim 24 depends from claim 9, and specifies that the fertilizing step comprises self-pollination, respectively. Support for new claim 24 is found in the specification at page 27, lines 7-14. No new matter has been added by way of these amendments.

The Examiner has found the declaration to be defective. A substitute Declaration (in three parts) is submitted herewith, properly claiming priority to U.S. Provisional Application No. 60/057,982 under 35 U.S.C. § 119(e).

Claims 9 and 20-23 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention. In particular, the Examiner has found that claims 9 and 20-23 lack essential steps. Claim 9 (and its dependent claims 20-23) has been amended to add the steps of culturing the plant cells to produce the transgenic plant; expressing the recombinase; expressing the compound; and extracting the compound.

The Examiner has further rejected claim 9 because the Examiner finds the terms "biosynthetically producing" and "biologically detrimental" to be unclear. Claim 9 has been amended to replace "biosynthetically producing" with "producing." Furthermore, "a biologically detrimental compound" has been amended to "a compound that is detrimental to the plant." Finally, as suggested by the Examiner, "becomes operably linked" has been replaced with "is operably linked." Applicants believe that all rejections under 35 U.S.C. § 112, second paragraph, have been adequately addressed. Accordingly, applicants request withdrawal of these rejections.

Claims 9 and 20-23 have been rejected under 35 U.S.C. § 112, first paragraph. According to the Examiner, the specification would be enabling for a method that "includes the steps of culturing plant cells so as to produce a fertile transgenic plant from plant cells; self-pollinating said transgenic plant; expressing the recombinase in the plant; and producing valuable compounds. Applicants have amended claim 9 (and its dependent claims 20-23) to add the steps suggested by the Examiner, with the exception of self-pollination. Applicants respectfully submit that self-pollination is not required to produce a homozygous plant. Instead, sib-pollination or cross-pollination with similarly transformed plants would also produce homozygous plants.

Claims 9 and 20-22 stand rejected under 35 U.S.C. § 102(b), as being anticipated by Odell et al, U.S. Patent No. 5,658,772. According to the Examiner, Odell teaches the production of a plant producing a biologically detrimental compound by a promoter, a blocking sequence flanked by a pair of directly repeated site specific recombination sequences, and a structural gene coding for the biologically detrimental compound wherein the structural gene becomes operably linked to the promoter only after removal of the blocking sequence. The Examiner notes that Odell further teaches removal of the blocking sequences flanked by directly repeated site-specific recombination sequences in the presence of the recombinase gene, use of constitutive promoters, production of homozygous plants, genetic crosses of homozygous plants, and extractions of biological compounds from plant tissue. The Examiner concludes that Odell anticipates the present invention.

Odell teaches plant constructs wherein a disruption gene flanked by lox sites is introduced into a plant, and the disruption gene is only activated when crossed to a plant expressing Cre. This technique is used to produce seedless fruit.

However, Odell does not teach a method of expressing a gene encoding for a compound that is detrimental to the plant and is a commercially valuable product that is extracted

from the plant. In Odell, the detrimental compound (disruption gene product) is not extracted. Instead the detrimental compound is used in situ to disrupt seed development. With respect to the step of extracting the compound, the Examiner points to col. 15, lines 8-10 of Odell. However, col. 15, lines 8-10 teach extraction of RNA and DNA from the plant, compounds that are hardly detrimental to the plant. Thus, Odell does not teach or suggest a method of producing a commercially valuable compound by expressing the compound in a plant and extracting it therefrom, wherein the compound is detrimental to the plant. Applicants respectfully request withdrawal of this rejection.

Claims 9 and 20-23 stand rejected under 35 U.S.C. § 103(a) as being obvious over Kilby (1995) Plant Journal 8: 637-652, in view of Odell and Kilby (1993) Trends in Genetics 9: 413-421. According to the Examiner, Kilby (1995) teaches introducing into plant cells a DNA construct comprising a promoter, a blocking sequence, and a structural gene, where the blocking sequence is flanked by a pair of directly repeated site-specific recombination sequences and wherein the structural gene is operably linked to the promoter only after the removal of the blocking sequence. The Examiner notes that Kilby (1995) does not teach detrimental compounds. However, the Examiner points to Odell for the teaching of detrimental compounds. Furthermore, the Examiner finds that the toxicity of the detrimental biological compound itself provides motivation for blocking expression until the desired time. The Examiner also notes that Kilby (1993) suggests the strategy of gene activation only after removal of a blocking sequence as being particularly useful. The Examiner concludes that it would have been *prima facie* obvious to one of ordinary skill in the art at he time the inventions was made to use the strategy of expressing a biologically detrimental compound only after removal of a blocking sequence.

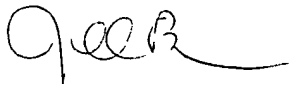
As noted by the Examiner, Kilby (1995) does not teach detrimental compounds. While Odell teaches the use of detrimental compounds to disrupt seed development, as discussed above the detrimental compound of Odell is used *in situ* to disrupt seed development. Odell does

not teach extraction of the detrimental compound. Also, while Kilby (1993) mentions the possibility of using similar constructs to study potentially harmful mutations, the methods described by Kilby (1993) are limited to studying the potentially harmful mutations, and there is no suggestion whatsoever of a method of producing a compound by extracting the gene product of the mutation in question. In sum, Kilby (1995) does not teach detrimental compounds and neither Odell nor Kilby (1993) teaches or suggests the production and extraction of a detrimental compound. Thus, none of the references, alone or in combination, teach or suggest use of a blocking sequence to introduce a gene into a plant wherein the gene product is a compound detrimental to the plant, and to extract the compound from the plant. Applicants respectfully request withdrawal of this rejection.

CONCLUSION

The application as amended, is believed to be in condition for allowance. Withdrawal of the rejections and passage of the application to issuance is requested.

Respectfully submitted,



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Appendix A
Version with markings to show changes made

Under 37 C.F.R. § 1.121(c)(1)(i), please amend claims 9 and 20-21 as follows:

9. (Twice Amended) A method for [biosynthetically] producing commercially valuable compounds, said method comprising the steps of

producing a fertile transgenic plant by introducing into plant cells a DNA construct comprising a promoter, a blocking sequence, and a structural gene coding for a [biologically detrimental] compound that is detrimental to the plant and is commercially valuable, said blocking sequence being flanked by a pair of directly repeated site-specific recombination sequences and wherein the structural gene [becomes] is operably linked to the promoter only after the removal of said blocking sequence, and culturing the plant cells to produce the transgenic plant;

[cross] fertilizing said transgenic plant to produce transgenic plants that are homozygous for the gene encoding said [biologically detrimental] compound;

crossing said [homozygous] transgenic plant homozygous for the gene encoding said compound with a plant having a DNA sequence comprising a gene encoding a site-specific recombinase that recognizes said site-specific recombination sequences to produce an F1 plant or seed;

expressing the recombinase in the F1 plant or seed;

expressing the compound; and

extracting the compound.

20. (Amended) The method of claim 9 wherein the [step of crossing said homozygous transgenic plant with a plant having a DNA sequence comprising a gene encoding a

site-specific recombinase produces an] expressing the compound step occurs in the F1 plant or seed [that expresses the biologically detrimental compound].

21. (Amended) The method of claim 20[, further comprising the step of] wherein the extracting step comprises extracting the compound from the F1 plant or seed.